

### **REMARKS/ARGUMENTS**

Claims 74-80 and 82-106 are pending in the application. Claims 74-80 and 82-83 have been allowed. The Applicants thank the Examiner for indication of allowable subject matter. Applicants reserve the right to prosecute any cancelled or withdrawn subject matter in one or more continuation or divisional application.

#### **Claim Objections**

Claims 98 and 99 have been objected to for failing to further limit the subject matter of a previous claim. The Applicants have amended claims 98 and 99 to place both in proper dependent form. The Examiner states that the process of delivering the permeant does not further limit the system which includes a permeant and a heat source. The Applicants submit that claims 98 and 99 as amended are directed towards a system and no longer a process. The Applicants submit that claim 98 further limits the system of claim 92 by specifying the biological membrane to be breached as the epidermis (claim 98). Furthermore, claim 99 limits claim 98 to a selected biological surface area greater than the total area of the micropores. Both of these are limitations in that one is able to envision alternative results, for example the biological membrane as other than epidermal tissue or a surface area equal to the total area of the micropores, all of which are not encompassed by amended claims 98 and 99.

The Examiner has objected to claims 94 and 95 as unclear as to what further structural limitations have been set forth. Claim 94 has been amended to recite, "wherein the organism is an animal" and claim 95 to be further limited to, "wherein the animal is a human." The Applicants believe this should obviate the Examiner's objection. The Examiner also states that the claims merely define the intended use of the system. The Applicants respectfully argue that the two system claims are not directed to an intended use and ask that the Examiner provide further clarification if the present amendments do not obviate the objection.

#### **Double Patenting**

Claim 106 has been objected to as a substantial duplicate of claim 91. The Applicants have canceled claim 106, thus rendering the rejection moot.

### **Claim Rejections under 35 U.S.C. § 102**

Claims 91 and 106 have been rejected under 35 U.S.C. § 102(b) as “being anticipated by Applicant’s admission of the prior art.” The Examiner states that the Applicant “discloses it is known to use a heat source to create a micropore.” The Applicants respectfully submit that it is unclear what admission of the prior art the Examiner is referring to. The Examiner has not cited any prior art, nor are the Applicants aware of any prior art that discloses amended claim 91’s recitation of a “bioactive agent is put in contact with the selected area in a form selected from the group consisting of a tablet and a bio-erodable matrix.” The Applicants therefore request that the rejection to claim 91 be withdrawn. Claim 106 has been cancelled in this response thus rendering the rejection to this claim moot.

### **Claim Rejections under 35 U.S.C. § 103**

The Examiner has rejected claims 84-90 and 92-105 under 35 U.S.C. § 103(a) as being obvious over Applicant’s “admission of the prior art.” The Examiner states that claims 84-90 and 92-105 are obvious due to the Applicant’s previous disclosure that a heat source may be used to create a micropore. As above, the Applicants respectfully submit that it is unclear what admission of the prior art the Examiner is referring to. The Examiner has not cited any prior art, nor are the Applicants aware of any prior art that discloses claim 84’s recitation of “wherein the apparatus enables the dry powder formulation, when the dry powder formulation is put in contact with the selected area, to be taken up through the micropore into the organism, wherein the apparatus delivers the dry powder formulation into the organism.” The Applicants therefore request that the rejection to claims 84-90 be withdrawn. With respect to claims 92-99, the Examiner has not cited any prior art, nor are the Applicants aware of any prior art that discloses claim 92’s recitation of “and at a depth coincident with increased concentration of langerhans cells.” The Applicants therefore request that the rejection to claims 92-99 be withdrawn. Further, with respect to claims 100-105, the Examiner has not cited any prior art, nor are the Applicants aware of any prior art that discloses claim 100’s recitation of a system wherein “the system enables the dry powder formulation, when the dry powder formulation is put in contact with the selected area, to be taken up through the micropore into the organism, wherein the system

delivers the dry powder formulation into the organism.” The Applicants therefore request that the rejection to claims 100-105 be withdrawn.

If the Examiner believes there are other issues that may be resolved by telephone interview, or that there are any informalities remaining in the application that may be corrected by Examiner’s Amendment, a telephone call to the undersigned is respectfully solicited.

No additional fees are believed due, however the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment of fees to Deposit Account number 11-0980.

Respectfully submitted,

/MONIQUE N. KIERLIN-DUNCAN/

Monique N. Kierlin-Duncan, Ph.D.  
Reg. No. 63,101

KING & SPALDING LLP  
1180 Peachtree Street, N.E.  
Atlanta, Georgia 30309-3521  
Telephone (404) 572-2473  
Facsimile (404) 572-5134